

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

GEORGE SAGE-ALLISON AND
LU LU SAGE-ALLISON,

Plaintiffs,

v.

CIV No. 7-25 KG/GBW

NOVARTIS PHARMACEUTICALS CORP.

Defendant.

PROPOSED FINDINGS AND RECOMMENDED DISPOSITION

This matter is before the Court on Defendant's Summary Judgment Motion, Supplemental Summary Judgment Motion, and *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Non-Retained Experts. Having reviewed the pleadings and relevant law, and being fully advised, I recommend that the Court GRANT Defendant's Motions.

I. BACKGROUND

The facts of this case are set forth in the Magistrate Judge's PFRD filed November 11, 2013. *Doc. 53*.¹ As is relevant here, Plaintiff George Sage-Allison was suffering from prostate cancer with bone metastases when, in October 2004, he was prescribed Zometa®, an intravenous infusion bisphosphonate drug, to treat the attendant bone

¹ Citations to "Doc." without any attendant citation information refer to docket numbers in *Sage-Allison, et al. v. Novartis Pharmaceuticals Corp.*, 1:07-cv-00025-KG-GBW (D.N.M. Jan. 5, 2007).

lesions and prevent skeletal fractures. *Doc. 17* at 2.² Plaintiff alleges that, as a result of the treatment with Zometa®, Mr. Sage-Allison developed osteonecrosis of the jaw (ONJ).

Plaintiff initially brought this action in the First Judicial District Court of New Mexico on November 27, 2006. *Doc. 1, Ex. A*. Plaintiff alleged six causes of action including products liability; negligent misrepresentation; breach of express warranty; breach of implied warranty, merchantability, and fitness for a particular purpose; negligence and negligence per se; and strict liability.

On December 22, 2006, Plaintiff amended his Complaint to include Lu Lu Sage-Allison as a named Plaintiff and added a loss of consortium cause of action. *Doc. 1, Ex. C*. On January 5, 2007, Defendant Novartis Pharmaceuticals Corporation filed a Notice of Removal based on diversity jurisdiction. *Doc. 1*. On January 9, 2007, Defendant Novartis filed its Answer. *Doc. 5*. On March 5, 2007, the Judicial Panel on Multidistrict Litigation entered a Conditional Transfer Order transferring Plaintiffs' case to the Middle District of Tennessee for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *Doc. 7*.

On January 17, 2012, the Middle District of Tennessee filed a conditional remand order including adjudication of the instant summary judgment and related motions, including Defendant's pending *Daubert* motion. *Doc. 9*. On December 17, 2013, the

² Mr. Sage-Allison passed away on October 31, 2007. Statement of Facts, *MDL 1760 Plaintiffs, et al. v. MDL 1760 Defendants, et al.*, 3:06-md-01760 (M.D. Tenn. Nov. 1, 2011) *Doc. 5369 Ex. 88*.

Court permitted limited supplemental briefing on Defendant's motion for summary judgment. *Doc. 58*. Supplemental briefing was completed on February 3, 2014. *Doc. 65*.

II. THE LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) requires that a party seeking summary judgment demonstrate that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "In our circuit, the moving party carries the burden of showing beyond a reasonable doubt that it is entitled to summary judgment." *Trainor v. Apollo Metal Specialties, Inc.*, 318 F.3d 976, 979 (10th Cir. 2002) (quoting *Hicks v. City of Watonga*, 942 F.2d 737, 743 (10th Cir. 1991)) (internal quotations omitted).

Summary judgment is proper only if a reasonable trier of fact could not return a verdict for the nonmoving party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The movant bears the initial burden of "show[ing] that there is an absence of evidence to support the nonmoving party's case." *Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887, 891 (10th Cir. 1991) (citing *Celotex*, 477 U.S. at 325). Once the movant meets this burden, Rule 56(e) requires the non-moving party to designate specific facts showing that "there are . . . genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Celotex*, 477 U.S. at 324. "An issue is 'genuine' if there is sufficient evidence on each side so that a rational trier of fact could

resolve the issue either way. An issue of fact is ‘material’ if under the substantive law it is essential to the proper disposition of the claim.” *Thom v. Bristol Myers Squibb Co.*, 353 F.3d 848, 851 (10th Cir. 2003) (internal citation omitted). “A party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record . . .” Fed. R. Civ. P. 56(c)(1)(A). All material facts set forth in the motion and response which are not specifically controverted are deemed undisputed. D.N.M.LR-Civ. 56.1(b).

The court must adhere to three principles when evaluating a motion for summary judgment. First, the court’s role is not to weigh the evidence, but to assess the threshold issue whether a genuine issue exists as to material facts requiring a trial. *See Liberty Lobby*, 477 U.S. at 249. Second, the court must resolve all reasonable inferences and doubts in favor of the non-moving party, and construe all evidence in the light most favorable to the non-moving party. *See Hunt v. Cromartie*, 526 U.S. 541, 551–54 (1999). Third, the court cannot decide any issues of credibility. *See Liberty Lobby*, 477 U.S. at 255. However, if the non-moving party’s story “is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for the purposes of ruling on a motion for summary judgment.” *Scott v. Harris*, 550 U.S. 372, 380 (2007). In the end, “to survive the . . . motion, [the nonmovant] need only present evidence from which a jury might return a verdict in his favor.” *Liberty Lobby*, 477 U.S. at at 257.

III. STATEMENT OF UNDISPUTED FACTS³

BACKGROUND OF ZOMETA® REGULATION

1. Zometa® is a bisphosphonate manufactured by Defendant Novartis Pharmaceuticals Corporation. It is prescribed to reduce or delay bone fractures in patients being treated for, among other conditions, hypercalcemia of malignancy, metastatic cancer, and prostate cancer. Statement of Facts, *MDL 1760 Plaintiffs, et al. v. MDL 1760 Defendants, et al.*, 3:06-md-01760 (M.D. Tenn. Nov. 1, 2011) *doc.* 5369, Ex. 1.
2. Zometa® was approved for the treatment of hypercalcemia of malignancy by the Food and Drug Administration (FDA) in August 2001 and for bone metastases associated with prostate cancer in February 2002. *Id.*, *doc.* 5369, Exs. 2, 3.
3. Bisphosphonates, including Zometa®, can cause ONJ. Medical comorbidities of ONJ include previous or maintenance chemotherapy and dexamethasone. Dental comorbidities include poor dentition. *Id.*, *doc.* 5369, Ex. 12.
4. On September 26, 2003, based on Defendant's receipt of information from post-marketing reports, MedWatch forms, and external investigations, Defendant notified the FDA that it was revising its Zometa® labeling to include the following language: "Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well

³ The sources of the undisputed facts in this case are drawn from the Middle District of Tennessee docket Nos. 3:06-md-1760 and 3:07-cv-00238.

documented multiple risk factors. It is not possible to determine if these events are related to Zometa® or other bisphosphonates, to concomitant drugs or other therapies (e.g. chemotherapy, radiotherapy, corticosteroid), to patients' underlying disease, or to other co-morbid risk factors (e.g. anemia, infection, pre-existing oral disease)." *Id.*, doc. 5369, Exs. 17, 21, 22, 26.

5. In February 2004, Defendant further revised the Zometa® label to include the following language: "Although causality [of ONJ] cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged." *Id.*, doc. 5369, Ex. 29.

6. On February 27, 2004, the FDA approved this revision of the Zometa® label:

Cases of osteonecrosis (primarily of the jaws) have been reported in patients treated with bisphosphonates. The majority of reported cases are in cancer patients attendant to a dental procedure. Osteonecrosis of the jaws has multiple well documented risk factors including a diagnosis of cancer, concomitant therapies (e.g. chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions (e.g. anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged.

Id., doc. 5369, Ex. 29

7. On September 24, 2004, Defendant again revised the Zometa® package insert to explicitly advise that prior to the initiation of treatment with the drug, patients should undergo a dental examination and preventative treatment as necessary. The insert also advised patients receiving the drug should "avoid invasive dental

procedures if possible.” *Id.*, doc. 5369, Ex. 30. On the same, day, Defendant sent a

“Dear Doctor” letter⁴ to healthcare providers advising them of the label change.

Dr. Jan Merin was one of the physicians on that mailing list. *Id.*, doc. 5369, Ex 31.

This insert was the operative insert in October 2004. *Id.*, doc. 5369, Exs. 32, 33.

8. In September 2007, the Zometa® label was revised again to contain more extensive warnings about the risk of ONJ. *Sage-Allison v. Novartis Pharm. Corp., et al.*, 3:07-cv-00238 (M.D. Tenn. Dec. 30, 2011), doc. 51, Ex. 1.
9. Zometa® remains an FDA-approved medication. 3:06-md-01760, doc. 5369, Ex. 5.

PLAINTIFF’S MEDICAL HISTORY

10. Plaintiff was initially diagnosed with prostate cancer in October 1998, and with likely metastatic disease in November 2001. *Id.*, doc. 5369, Exs. 43, 44, 47.
11. In April 2003, Plaintiff received a bone scan that indicated, among other things, that he had dental disease and metastatic cancer. *Id.*, doc. 5369, Ex. 49. At that time, he began to receive Lupron (a hormonal therapy) to treat his metastatic cancer. *Id.*, doc. 5369, Exs. 49, 50.
12. In December 2003, Plaintiff began treatment with Casodex for his cancer. *Id.*, doc. 5369, Ex. 51.

⁴ A “Dear Doctor” letter is “correspondence — often in the form of a mass mailing from the manufacturer or distributor of a human drug or biologic or from FDA — intended to alert physicians and other health care providers about important new or updated information regarding a human drug or biologic (hereafter “drug” and “product” refer to both biologic and small molecule drug products).” See www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm233769.pdf

13. In August 2004, testing on Plaintiff indicated that hormonal therapy was no longer effective and Plaintiff was referred to Dr. Jan Merin, an oncologist. *Id.*, *doc.* 5369, Ex. 52; 1:07-cv-00025, *doc.* 61 Ex. 1 at 1:7-11.
14. In September 2004, Plaintiff began seeing Dr. Merin for cancer treatment. 3:06-md-01760, *doc.* 5369, Ex. 53. At that time, Plaintiff reported to Dr. Merin that he had “significant pain his hips, bilateral femurs, right shoulder, and some slight weakness and his legs . . .” *Id.*, *doc.* 5369, Ex. 53. A bone scan performed at the same time, compared to the bone scan performed in April 2003, indicated skeletal metastatic disease in Plaintiff’s torso. *Id.*, *doc.* 5369, Ex. 54.
15. In October 2004, Dr. Merin prescribed Plaintiff twelve cycles of Zometa®. *Id.*, *doc.* 5369, Ex. 55. Plaintiff took Zometa® from that date until September 2005. *Id.*, *doc.* 5369, Exs. 56, 57, 65, 66, 67.
16. In October 2005, Plaintiff reported to Dr. Merin that for “two or three months [prior to October 2005] he has been having difficulty with left jaw pain and tooth pain on and off. . . he has had intermittent infections with that tooth . . .” *Id.*, *doc.* 5369, Ex. 67. Plaintiff had been referred to an oral surgeon who “removed some bone.” *Id.* Dr. Merin identified the condition as likely being ONJ and hypothesized, but did not make a formal diagnosis that the cause of Plaintiff’s dental issues was a combination of his chemotherapy, prednisone, poor dental hygiene, and Zometa®. *Id.*; 1:07-cv-00025, *Doc.* 61, Ex. 1 at 51:5-16; 58:5-11, 63:5-

16. Because of Plaintiff's dental issues, Dr. Merin discontinued the Zometa ®.

3:06-md-01760, *doc. 5369*, Exs. 67, 68.

17. Dr. Merin testified she was not an expert with ONJ and she does not treat ONJ or other oral health issues. 1:07-cv-00025, *doc. 61* Ex. 1 at 63:22-23; 81:18-23. She further testified she is not an expert on bisphosphonates, although she does use them frequently in her practice. *Id.*, *doc. 61* Ex. 1 at 81:18-20.

18. In February 2006, Dr. Merin noted that Plaintiff's response to his cancer treatment was worsening and recommended that he enter hospice. 3:06-md-01760, *doc. 5369*, Ex. 73.

19. On April 21, 2006, Plaintiff sought a second opinion on his cancer treatment from Dr. Peter Lindberg of the Los Alamos Health Clinic in Los Alamos, New Mexico. *Id.*, *doc. 5369*, Ex. 74.

20. On that April 21, 2006 visit, Dr. Lindberg stated that he observed Plaintiff's exposed jaw bone. From that observation, he diagnosed Plaintiff with ONJ. He further stated that he did not perform a differential diagnosis on Plaintiff's jaw himself, instead basing the diagnosis on Plaintiff's medical records and Plaintiff's self-reporting of his condition. Dr. Lindberg further testified that he did not consider himself an expert on ONJ, and that at no point in the course of his treatment of Plaintiff did he perform any biopsies of Plaintiff's oral tissue. Finally, he stated that if he encountered a patient he believed to have ONJ, that

he would refer treatment of that condition to another physician. 3:06-md-01760, *doc. 5369*, Ex. 8 43:17-24; 3:07-cv-00238, *doc. 51*, Ex. 20 at 45:3-46:3; 55:1-15; 81:10-23.

21. In June 2006, Plaintiff began a new course of chemotherapy, including high doses of corticosteroids. 3:06-md-01760, *doc. 5369*, Ex. 8 43:17-24.

22. In July 2006, Dr. Lindberg observed a second lesion in Plaintiff's mouth, but did not observe exposed bone at that site. 3:07-cv-00238, *doc. 51*, Ex. 20 at 54:2-20. At that time, he did not perform any testing to determine if Plaintiff had an infection of the mouth. *Id.*, *doc. 51*, Ex. 20 at 56:6-10. Nor did he perform a differential diagnosis as to the cause of this lesion. *Id.*, *doc. 51*, Ex. 20 at 5 57:12-17.

23. Plaintiff received chemotherapy throughout the remainder of 2006 and through mid 2007. 3:06-md-01760, *doc. 5369*, Exs. 75, 77, 78, 79, 81, 85.

24. Because of ongoing bone pain, Plaintiff was again treated with Zometa® beginning July 23, 2007. *Id.*, *doc. 5369*, Ex. 87

25. Plaintiff died on October 31, 2007. The cause of death listed was prostate cancer. *Id.*, *doc. 5369*, Ex. 88.

PLAINTIFF'S DENTAL HEALTH HISTORY

26. In August 1997 Plaintiff began to receive dental treatment from Dr. Mark Johnson, D.D.S. *Id.*, *doc. 5369*, Ex. 89 at 9:18-21. At that time, Dr. Johnson observed that Plaintiff presented with poor dentition and moderate to severe

periodontal disease. 3:07-cv-00238, *doc. 40* Ex. 6 at 24:12-25, 55:19-22. Plaintiff was noncompliant with treatment suggestions for his oral hygiene and continued to exhibit poor oral health through August 30, 2005. *Id.*, *doc. 5369*, Exs. 89, 90, 91, 92, 93, 94, 95; 3:07-cv-00238 *doc. 40* Ex. 6 at 31:17-25; 39:3-41:15; 55:19-22.

27. Dr. Johnson testified that he is not familiar with the effects of the drug Zometa®, bisphosphonate therapy in the context of bone metastasis treatment, and that he does not consider himself an expert in ONJ. 3:07-cv-00238, *doc. 40*, Ex. 6 at 6:12-24; 57:15-23. He further testified that he did not, at any point, perform a differential diagnosis on Plaintiff's jaw. *Id.*, *doc. 40* Ex. 6 at 53:14-17.

28. In August 2003, Plaintiff was referred to Dr. Stephen Christiansen D.D.S., an oral surgeon. *Id.*, *doc. 54* at 61. Dr. Christiansen extracted Plaintiff's tooth number 2. *Id.* Dr. Christiansen did not recall the state of Plaintiff's oral health at the time of this extraction. *Id.*

29. On September 27, 2005 Plaintiff was again treated by Dr. Christiansen for a problem with his tooth number 18. 3:06-md-01760, *Doc. 5369*, Ex. 96 at 17:1-7.

30. During that session, Dr. Christiansen observed an area of exposed jaw bone approximately .75 inches in size. *Id.* at 18:11-19; 18:25-19:4. Plaintiff reported to his dentist that the bone exposure had been present for at least a year preceding the examination. *Id.* at 19:12-16. Dr. Christiansen did not biopsy the exposed bone, nor did he determine that the bone was necrotic, although he stated he

removed “dead” bone. *Id.* at 18:17-19; 25:4-8. Dr. Christiansen could not recall if he observed any sign of infection at the site of tooth number 18. *Id.* at 20:25-21:6.

31. Pursuant to his examination, Dr. Christiansen extracted tooth number 18. *Id.* at 21:7-8.

32. At that time, Dr. Christiansen did not make any further diagnosis, nor undertake any further investigation, of the etiology of Plaintiff’s jaw condition, including any determination of the role of Plaintiff’s chemotherapy in any existing jaw disease. *Id.* at 21:17-22:3; 22:12-23.

33. Plaintiff received a jaw x-ray on October 10, 2005. 3:07-cv-00238, *doc. 51*, Ex. 21 at 32:14-24. From that x-ray, Dr. Christiansen stated that he could observe bone loss, but also testified that bone loss could be attributable to a variety of causes, including periodontal disease and osteomyelitis. *Id.* at 32:14-34:8.

34. On October 11, 2005, Dr. Christiansen again treated Plaintiff, at which time he observed that there continued to be exposed bone near the tooth number 18 site. *Id.* at 27:15-20.

35. On October 18, 2005, Dr. Christiansen again treated Plaintiff, at which time he observed that there continued to be exposed bone near the tooth number 18 site. *Id.* at 29:17-30:7. He further observed that the bone appeared to be “brittle.” *Id.*

36. On October 31, 2005, Dr. Christiansen again treated Plaintiff, at which time he observed that there continued to be exposed bone near the tooth number 18 site,

but did not note whether there was any difference in the size of the exposed bone as compared to the October 18, 2005 visit. *Id.* at 32:2-9.

37. On November 11, 2005, Dr. Christiansen again treated Plaintiff, removing some bone from Plaintiff's jaw. 3:07-cv-00238, *doc. 51*, Ex. 21 at at 35:4-7.

38. On December 1, 2005, Dr. Christiansen again treated Plaintiff, at which time he observed that the area of exposed bone at the site of tooth number 18 was not healing. *Id.* at 35:19-25.

39. On December 16, 2005, Dr. Christiansen again treated Plaintiff for his exposed bone. *Id.* at 37:12-19.

40. Twice in January 2006, Dr. Christiansen observed that there continued to be exposed bone near the tooth number 18 site, but did not note whether there was any difference in the size of the exposed bone as compared to Plaintiff's prior visits. *Id.* at 38:1-39:7.

41. In May 2006, Dr. Christiansen again treated Plaintiff, at which point he observed that Plaintiff continued to have exposed bone, which he again failed to compare in size to prior visits. *Id.* 39:16-40:5.

42. At his deposition, Dr. Christiansen testified that "there can be lots of reasons for exposed bone" in individuals, including, but not limited to trauma and poor dental hygiene. *Id.* at 24:1-9.

43. Dr. Christiansen testified that he does not consider himself an expert on the diagnosis or treatment of ONJ. 3:07-cv-00238, *doc. 51*, Ex. 21 at 6:17-20; 7:17-21.
44. Throughout the remainder of 2005 and early 2006, Plaintiff continued to exhibit symptoms of ONJ, although in December 2005 Plaintiff's medical records indicated that the diseased bone was mainly brittle rather than necrotic. 3:06-md-01760, *doc. 5369*, Exs. 69, 70, 71, 73.

IV. ANALYSIS

Defendant moves for summary judgment on all of Plaintiff's causes of action.⁵ Defendant also moves to exclude specific causation testimony provided by Plaintiff's non-retained experts under *Daubert*. For the following reasons, I recommend that the Court GRANT Defendant's Motions.

A. Defendant's *Daubert* Motion Should be Granted

In a toxic tort case such as the instant matter, a plaintiff must demonstrate both general causation (whether a substance is capable of causing the alleged injury) and specific causation (whether the substance at issue actually caused the plaintiff's injury). *Farris v. Intel Corp.*, 593 F. Supp. 2d 1174, 1186 (D.N.M. 2007). Defendant argues that Plaintiff has failed to introduce admissible evidence, expert or otherwise, of specific causation. Namely, Plaintiff has failed to show that (1) George-Sage Allison's jaw condition was, in fact, ONJ, and (2) that even if, for the sake of argument, he had ONJ,

⁵ I note that Plaintiff has withdrawn her express warranty and negligence per se causes of actions, and therefore will not address them here. *See* 3:07-cv-00238, *doc. 52* at 24.

that Zometa® caused it. Plaintiff responds that her non-retained expert testimony, along with the relevant medical records, demonstrate that George Sage-Allison did have ONJ and that his ONJ that could only have been caused by Zometa®.

Plaintiff has not designated retained expert witnesses who can testify to external medical/dental causation of Plaintiff's oral condition. Instead, Plaintiff offers four healthcare professionals as treating physician witnesses: Drs. Merin and Lindberg, both oncologists, and Drs. Johnson and Christiansen, both dentists. 3:07-cv-00238, *doc. 40*, Ex. 1 at 1. Plaintiff argues that these physicians are hybrid witnesses able to testify, based on their personal knowledge and treatment of Plaintiff, that he "suffered from ONJ caused by Zometa®" and that such testimony is sufficient to demonstrate specific causation. 3:07-cv-00238, *doc. 52* at 15-16.

Defendant, in its *Daubert* Motion, first contends that because none of these witnesses are experts in the diagnosis or causation of ONJ, any testimony from them about Plaintiff's jaw condition being ONJ or caused by Zometa® should be excluded under Federal Rule of Evidence 702 on the basis of unreliability. 3:07-cv-00238, *doc. 40* at 9-10. It also argues that as treating physician witnesses, the testimony of these physicians is limited to their direct treatment of Plaintiff. *Id.* at 11. Since none of these physicians "conclude, diagnose, or opine to a reasonable degree of medical certainty that Mr. Sage-Allison developed ONJ as a result of taking Zometa®," their testimony should be excluded for failing to advance a material aspect of Plaintiff's case. *Id.*

Finally, Defendant argues that Dr. Lindberg's testimony about Plaintiff having ONJ caused by Zometa® should be excluded because he failed to perform a differential diagnosis on Plaintiff's jaw, and Dr. Merin's testimony should be excluded because Plaintiff fails to identify an admissible causation opinion. *Id.* at 13-14

i. Admissibility of Lay and Expert Witness Testimony of Treating Physicians

Federal Rule of Evidence 701 allows lay opinion testimony that is "(a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based in scientific, technical or other specialized knowledge within the scope of [Federal] Rule [of Evidence] 702."

Federal Rule of Evidence 702 allows expert opinion testimony where "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." As the Supreme Court explained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the trial court should only admit such expert testimony when it is satisfied that (1) the expert is competent and qualified to testify regarding the subject matter of his testimony; (2) the methodology by which the expert reached his conclusions is sufficiently reliable; and (3) the expert, through scientific, technical or specialized expertise, provides testimony that assists the trier of fact to understand the evidence or determine a fact in issue. 509 U.S. 579, 590-595 (1993); *see also Farris*, 593 F. Supp. 2d at 1181 n.3 (explaining that based on the Supreme Court's reasoning in *Kumho*

Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149 (1999), *Daubert* applies to treating physicians offered as “hybrid” witnesses).

A treating physician’s testimony as it pertains to the treatment of the patient at issue is lay testimony governed by Rule 701. *Montoya v. Sheldon*, 286 F.R.D. 602, 619 (D.N.M. 2012) (“Because [the treating physician] interacted with [the patient] in his treatment, she is a lay witness and may testify to her treatment of [plaintiff], as long as the testimony is ‘rationally based’ on her perceptions at the time of the treatment and helpful to determining a fact in issue.”).⁶ A treating physician testifying under Rule 701 may not opine as to causation of a medical condition because such testimony necessarily involves “knowledge derived from previous professional experience [, which] falls squarely within the scope of Rule 702 and thus by definition outside of Rule 701.” *James River Ins. Co. v. Rapid Funding, LLC*, 658 F.3d 1207, 1215 (10th Cir. 2011) (quoting *United States v. Smith*, 640 F.3d 358, 365 (D.C. Cir. 2011)).

ii. *Dr. Merin*

Plaintiff contends that Dr. Merin is a qualified expert under Federal Rule of Evidence 702 because she was Plaintiff’s treating physician. 3:07-cv-00238 doc. 53 at 7.

As discussed above, Dr. Merin is a medical oncologist. Undisputed Fact (UF) 13. She

⁶ Judge Browning, in *Montoya*, provides this salient example by Professor Steven Saltzberg to illustrate the difference between permissible 701 treating physician testimony and impermissible 702 expert testimony: “When the physician testifies that the plaintiff was coughing and running a fever, this is lay witness testimony governed by Rule 701. However, if the physician also testifies that he diagnosed the patient as having Reactive Airways Dysfunction Syndrome caused by exposure to a toxic chemical, then this is testimony based on scientific, technical, or other specialized knowledge and must be qualified under Rule 702.” 286 F.R.D. at 619.

has testified that she has no particular expertise in (1) dental health; (2) bisphosphonates; or (3) diagnosis on ONJ. UF 17. She further states that she did not diagnose Plaintiff with ONJ – that all she did was note her impression that Plaintiff’s jaw condition could be ONJ.⁷ Dr. Merin ceased Plaintiff’s Zometa® treatment because she believed ONJ could potentially be the result of some combination of Plaintiff’s use of Zometa®, Taxoere, and prednisone. UF 16. At no point did she attempt to diagnose Plaintiff, by biopsy or other method of testing, with ONJ. Nor did she conduct any kind of differential diagnosis to arrive at the conclusion that Zometa®, and not any of the other medications implicated by her impression, caused his jaw condition.

In spite of these facts, Plaintiff blithely asserts that “such opinion testimony is sufficient to prove the element of case specific causation in this case.” *Doc. 62* at 2. Plaintiff is incorrect. First, Plaintiff has not submitted Dr. Merin as an expert witness under Rule 702, and therefore she cannot provide opinion testimony as to the medical cause of Plaintiff’s oral health condition. Second, though Dr. Merin could perhaps, based on her extensive experience with bisphosphonates, testify as a lay witness to the occurrence of ONJ in patients using Zometa® in her practice, Dr. Merin has not provided such testimony. In fact, she disavows any expertise in diagnosing ONJ. Nor is there is anything on the record before this Court as to how often she has seen ONJ

⁷ Plaintiff’s argument regarding Dr. Merin’s opinion rests heavily on the fact that Dr. Merin noted this impression in the part of her medical records labeled “Diagnoses.” However, Dr. Merin explicitly states that she did not intend to diagnose ONJ, nor is she qualified to diagnose ONJ. UFs 16, 17; *doc. 62* Ex. 1 at 63:5-8.

occur in patients receiving Zometa®. To the extent, therefore, that Plaintiff seeks to introduce Dr. Merin's medical notes on her observations of Plaintiff's jaw condition and its potential link to Zometa® as expert testimony in support of causation, Plaintiff should not be permitted to do so.

iii. Dr. Lindberg

Like Dr. Merin, Dr. Lindberg is a medical oncologist. UF 19. Also like Dr. Merin, Dr. Lindberg's "diagnosis" of Plaintiff's jaw condition is best characterized as an impression. As Dr. Lindberg himself testified, he observed Plaintiff's exposed jaw bone, discussed Plaintiff's course of medications, consulted with the patient, reviewed Plaintiff's medical records, and on that basis diagnosed Plaintiff with ONJ. UF 20. He admits that he has no particular expertise in ONJ. *Id.* He further admits that he performed no testing on Plaintiff's jaw bone or surrounding oral tissue that would allow him to actually determine the cause of the observed oral lesion. *Id.* The only thing that Dr. Lindberg can testify to, in light of the foregoing, is that he observed the exposed bone in Plaintiff's jaw. Therefore the issue is not, as Plaintiff contends, the fact that Dr. Lindberg did not perform a differential diagnosis on Plaintiff's jaw, or fail to rule out other potential causes. 3:07-cv-00238, *doc.* 53 at 12. The problem with Dr. Lindberg's proffered testimony is far more fundamental: he has no scientific basis on which to present any testimony other than his observation that Plaintiff had oral lesions of unspecified origin, and his speculation as to their potential causes based on his

treatment of Plaintiff. *See Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) (declining to consider expert testimony that failed to “include a description of the method used to arrive at the [scientific conclusion] and scientific data supporting the determination. The expert's assurance that the methodology and supporting data is reliable will not suffice.”). Plaintiff has failed to demonstrate that Dr. Lindberg is qualified as an expert under Rule 702, and as such, his proffered expert testimony as to specific causation should be excluded.

iv. Dr. Johnson

While a dental professional, Dr. Johnson has specifically disavowed an expertise with ONJ and any familiarity with the effects of bisphosphonate. UF 27. His treatment records do not indicate that he treated Plaintiff for anything other than his ongoing oral health issues arising from poor dentition. *Id.* Defendant Johnson should not, therefore, be permitted to testify as a Rule 702 expert by this Court.

v. Dr. Christiansen

Dr. Christiansen provided treatment for Plaintiff's oral health issues between August 2003 and May 2006. In September 2005, he observed that Plaintiff had an oral lesion with exposed bone. UF 30. At that time, he performed no testing or diagnosis on the exposed bone or surrounding oral tissue to determine the cause of the lesion, in spite of stating that he was removing “dead” bone. *Id.* From September 2005 through May 2006, Dr. Christiansen continued to observe that Plaintiff had issues with his oral

health, including exposed and “brittle” bone, but still performed no testing on the bone or tissue in that area of Plaintiff’s mouth. UFs 34-41. Further, at no point did Dr. Christiansen measure the lesion first observed in September 2005 to study its growth or diminution. *Id.* Indeed, at no point in the course of his treatment of Plaintiff did he study the etiology of the lesion. *Id.* Other than extracting Plaintiff’s tooth number 18, debriding Plaintiff’s jawbone, and noting the presence of the lesion, Dr. Christiansen did not provide any treatment of the lesion or surrounding tissue.

More importantly, Dr. Christiansen testified that the exposed bone observed in Plaintiff could have been caused by a variety of factors, including poor dental hygiene, which was a known issue for Plaintiff. UFs 26, 42. Dr. Christiansen’s failure to perform any testing to identify the cause of Plaintiff’s oral condition, in light of that observation, is fatal to his ability to testify to specific causation. *See Farris*, 493 F. Supp. 2d at 1185 (in refusing to allow a treating physician to testify as to specific causation, this Court explained that “[the physician’s] failure . . . to rule out other potential causes of Plaintiff’s injury is especially problematic because the record reflects a number of other potential causes of this particular Plaintiff’s [injury]”). Plaintiff has failed to demonstrate that Dr. Christiansen can testify to specific causation under Rule 702.

B. Defendant's Motion for Summary Judgment Should be Granted

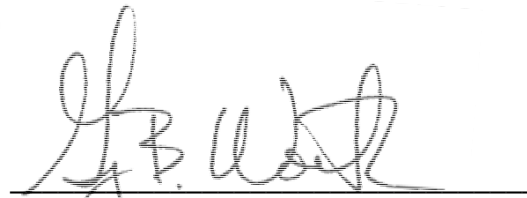
Each of Plaintiff's stated causes of action in the Complaint⁸, with the exception of the loss of consortium claim, requires that Plaintiff demonstrate specific causation. *Farris*, 593 F. Supp. 2d at 1186. In a toxic tort case, causation must be demonstrated through expert testimony. *Farris*, 93 F. Supp. 2d at 1186 (citing *Mitchell*, 165 F.3d at 78). In the absence of such expert testimony, dismissal on summary judgment is proper. *Miller v. Pfizer, Inc.*, 356 F.3d 1326, 1327 (10th Cir. 2004) (after losing the *Daubert* motion, Plaintiffs had "no expert [witness] to provide evidence of causation. Accordingly, the court granted summary judgment to [the defendant]."). For the reasons discussed in Section A, Plaintiff has failed to set forth qualifying expert testimony under Federal Rule of Evidence 702. Defendant's Motion for Summary Judgment as to these Counts should be GRANTED.

Finally, Plaintiff Lu Lu Sage-Allison contends that she has suffered loss of consortium because of the injury inflicted on Plaintiff George Sage-Allison by Zometa®. However, "[l]oss-of-consortium damages are contingent upon the injured person's entitlement to general damages." *Archer v. Roadrunner Trucking Inc.*, 930 P.2d 1155, 1160 (1996). Because Plaintiff has not demonstrated an entitlement to damages, this claim fails as matter of law.

⁸ Plaintiff alleges causes of action for product liability, strict liability and negligence. Under New Mexico law, product liability comes in two forms: strict product liability, or negligence. See *Armijo v. Ex Cam, Inc.*, 656 F. Supp. 771, 773-775 (D.N.M. 1988). I will therefore construe Plaintiff's apparently stand-alone products liability claim as incorporated into these two subsequent causes of action.

V. CONCLUSION

For the forgoing reasons, I recommend that the Court grant Defendant's *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Non-Retained Experts. I further recommend that the Court find that Defendant has met its burden of showing that it is entitled to judgment as a matter of law under Federal Rule of Civil Procedure 56 and that the Court grant Defendant's Motion for Summary Judgment.



GREGORY B. WORMUTH
UNITED STATES MAGISTRATE JUDGE

THE PARTIES ARE FURTHER NOTIFIED THAT WITHIN 14 DAYS OF SERVICE of a copy of these Proposed Findings and Recommended Disposition they may file written objections with the Clerk of the District Court pursuant to 28 U.S.C. § 636(b)(1). A party must file any objections with the Clerk of the District Court within the fourteen-day period if that party wants to have appellate review of the proposed findings and recommended disposition. If no objections are filed, no appellate review will be allowed.